claims under *35 U.S.C. § 102(b)* as anticipated by *U.S. Patent No. 4,341,220* to Perry and cited *U.S. Patent No. 4,991,579* to Allen. (*Id.*) The third ground for rejection was *35 U.S.C. § 112*, [*10] P 2. (*Id.* at 55-56). The examiner stated that "the claims are claimed so broadly and vaguely, it is difficult to understand just what the applicant is claiming." (*Id.* at 56). The examiner raised a number of concerns about the breadth and vagueness of the claims.

In March 17, 1992, the applicant (through Dr. Bucholz) submitted Amendment A, cancelling some claims, amending others, and adding one claim. (*Id.* at 64-76). Claim 16 in the application became claim 14 in the issued patent. Changes to that claim included the addition of the term "reference means" to the first step and the addition of a second step: "determining the position of the reference points of the head relative to the reference means so that the position of the tip relative to the reference points of the head is known." n2 (*Id.* at 67).

n2 "Head" was later changed to "body."

In the remarks section of Amendment A, Dr. Bucholz responded to the examiner's objections under *§ 112* as follows:

> With regard to head movement, it should [*11] be noted that the head need not remain stationary during the surgical procedure. The base ring is fixed to the head so that the relationship between the head and the microphone array is known because the relative position of the base ring with respect to the microphone array is known. Each time the surgeon wants to know the position of the probe, the base ring emitters are energized to establish the position of the base ring (and the head) immediately before the probe emitters are energized to establish the probe position. No fixed relationship between the array and the head is required. The only requirement is that the base ring (and the head) not move between the time the base ring emitters and the probe emitters are energized (about 1/4 second).

(*Id.* at 70-71). With respect to an alternate embodiment in which no base ring is fixed to the patient's head, Dr. Bucholz described the process for establishing the relationship between reference points, the head, and the array in this language: "The tip of the probe would be successively positioned at each of the pins and the probe emitters energized." (*Id.* at 72). Dr. Bucholz stated, "The Examiner is correct that the system [*12] would only work if the head is stationary between the time that the position of the reference points relative to the array are established and the time that the probe emitters are energized." (*Id.*)

Dr. Bucholz addressed the rejection for anticipation under *35 U.S.C. § 102(b)*, stating:

> Applicant submits that the invention addresses a significantly different problem than the prior art. Perry's *Patent 4,341,220* as well as Allen's *Patent 4,991,579* both address the ability to superimpose a coordinate system on head images. In contrast, the claims of this application recite the ability to localize the position of the tip of the surgical probe within the head on such a coordinate system placed on it. Neither Perry nor Allen address how they would localize a surgical instrument within the head during the course of surgery. . . . The claims of this application recite a technique and apparatus for the localization of an instrument within the patient's head by using emitters on the probe as well as an emitter attached to the patient's head. These emitters can be sound or light emitters. Applicant is not broadly claiming the right to superimpose a coordinate [*13] system on the head. This has been performed by prior art patents using fiducial markers such as a bird cage or the three point markers of the Allen patent.
>
> Perry's patent has almost no relevance to the current claims. Perry's invention simply creates a coordinate system on the patient's head using fiducial markers which are bolted to the head. This coordinate system requires the placement of a bulky box-like structure which again has no relationship to the free-hand technique of the invention using sound or light emitters on the probe. Perry makes no comments as to how a surgical instrument could be located within his coordinate system.
>
> Therefore it is submitted that each of the claims is distinguishable over the cited references because these claims recite a

> surgical probe or structure for defining the position of the probe relative to the head. For example, claim 1 recites reference means and a surgical probe, neither of which is shown in any of the patents cited by the Examiner. Furthermore, claim 1 recites first and second means for determining relative positions as well as translating means which allow the selection of an image corresponding to the position of the tip [*14] of the probe. Claim 16 [which issued as claim 14] is a method claim which parallels claim 1 and is similarly patentable over the cited references.

(Ex. A-8 at 74-75).

Almost three years later, the *454 patent* issued, dated January 24, 1995.

Argument-based prosecution history estoppel

BrainLAB first contends that Dr. Bucholz, by his statements to the examiner, limited his claims to products and methods using emitters located on the probe and the patient. [HN3] To invoke argument-based prosecution history estoppel, the prosecution history must evince a clear and unmistakeable surrender of subject matter. *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373, 1377 (Fed. Cir. 1999)*. The test is an objective one. The inquiry is "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Aquatex Indus., 419 F.3d at 1382* (quoting *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998))*.

In telling the examiner that the invention uses emitters on the probe and the head, Dr. Bucholz made his claims more definite and sought to overcome objections to the specification. [*15] Additionally, Dr. Bucholz distinguished the prior art patents by emphasizing the activation of emitters on the probe and the patient as the technique and apparatus for localizing an instrument within the patient's head during the course of surgery. A person reasonably skilled in the art of navigational surgery reviewing this prosecution history would reasonably believe that Dr. Bucholz was limiting the claim to require the activation of emitters on the probe and the patient to localize the surgical instrument.

As set forth *infra*, BrainLAB's products have infrared lighting on the camera housing and light reflecting markers on the surgical tools, to localize the instruments during surgery. The plaintiffs' witness Dr. Eric Grimson attempted to brush aside the difference by saying that in the science of physics, "emittance" is used in measuring how much energy comes off an object over a region of that object, and that the source of the energy is irrelevant to such a measurement. (Tr. at 828:6-22; 2470:11 -- 2471:14). That testimony was irrelevant. The question is not what an academic physicist would understand; it is what a person of reasonable skill in the art of navigational surgery [*16] would understand at the time and there is nothing else in the record to suggest that an emitter should be understood to mean anything other than its common language usage as describing the giving out or sending out of energy. What is relevant is how surgery is to be performed using the Bucholz method. Dr. Bucholz' statements to the examiner did not use the word "emittance." Dr. Bucholz repeatedly told the examiner that his invention uses emitters that are "energized" to establish positions of the head and the probe. n3 Dr. Bucholz is a surgeon, not a physicist.

> n3 Dr. Bucholz told the examiner that the method of claim 14 parallels claim 1, an apparatus claim. His statements about probe emitters apply to his method, as well as to the apparatus of claim 1.

Amendment-based prosecution history estoppel

[HN4] A narrowing amendment made to satisfy any requirement of the Patent Act gives rise to a presumption that the patentee surrendered the territory between the original claim and the amended claim. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 740, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002)*. [*17] "When . . . the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent. . . . His decision to . . . submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim." *Id. at 733-34*.

[HN5] "The first question in a prosecution history estoppel inquiry is whether an amendment filed in the [PTO] has narrowed the literal scope of a claim." *Festo, 344 F.3d at 1366* (citing *Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1356 (Fed. Cir. 2003))*. A narrowing amendment may occur when a preexisting claim limitation is narrowed by amendment or when a new claim limitation is added by amendment. *See Honeywell Int'l v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1141 (Fed. Cir. 2004)* (*en banc*).

Here the addition of the term "reference means" added a new claim limitation. A step was also added to the claim. This amendment was a narrowing [*18] one.

[HN6] "If. . . the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial one relating to patentability." *Festo, 344 F.3d at 1366*. The prosecution history of the Bucholz patent shows that the amendment was in response to rejections under *35 U.S.C. § § 102* and *112*. This amendment was a substantial one related to patentability.

[HN7] "The third question . . . addresses the scope of the subject matter surrendered by the narrowing amendment." *Festo, 344 F.3d at 1367*. There is a presumption that the patentee surrendered all territory between the original claim limitation and the amended claim limitation. *Festo, 535 U.S. at 740*. The patentee may overcome the presumption by showing that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id. at 741*. The patentee may do so:

> by demonstrating that "the equivalent [would] have been unforeseeable at the time of the [amendment]," that "the rationale underlying the amendment [*19] [bore] no more than a tangential relation to the equivalent in question," or that "there [was] some other reason suggesting that the patentee could not reasonably expected to have described the insubstantial substitute in question."

Festo, 344 F.3d at 1365 (quoting *Festo, 535 U.S. at 740-41*). If the patentee fails to rebut the presumption, "then prosecution history estoppel bars the patentee from relying on the doctrine of equivalents for the accused element." *Festo, 344 F.3d at 1367*.

Because the examiner found the original claims to be so broad and vague that it was "difficult to understand just what the applicant is claiming," it is also difficult to determine the specific territory between the original claim and the amended claim. The question is whether at the time of the amendment a person skilled in the art of surgical navigation could reasonably be expected to have drafted a claim that would have literally encompassed what is now claimed to be equivalent.

[HN8] "The first criterion requires a patentee to show that an alleged equivalent would have been unforeseeable at the time of the amendment and thus beyond a fair [*20] interpretation of what was surrendered." *Festo, 344 F.3d at 1369* (internal quotations and citation omitted). The relevant time for evaluating whether the alleged equivalent was foreseeable is when the narrowing amendment was made. *Id. at 1365 n.2*. The date of this amendment was March 17, 1992, a year and a half after the original application.

A letter dated May 29, 1990, from Dr. Bucholz to Mr. Dean Schulz of Pixsys, shows that Dr. Bucholz was aware of the possibility of using optical tracking for surgical navigation even before the October 19, 1990 filing date. Dr. Bucholz wrote to Mr. Schulz, expressing interest in "your new 3d digitizer which uses light rather than sound." (Ex. 79). Dr. Bucholz' lab notebook shows that he foresaw optical tracking at least a year before the March 17, 1992 amendment. In an entry dated March 12, 1991, he wrote: "optical digitizer a success; still buggy, though; production model avail. June . . . array not that important, will change with optic." (Ex. A-22 at 11-12). Other testimony and documentary evidence confirms that optical tracking was foreseeable at the time of the amendment. Dr. Peter Heilbrun testified that [*21] medical professionals having an interest in image-guided surgery technology met in April 1991, and one of the topics for discussion was an optical system. (Tr. at 625:21 -- 629:12; Ex. E-19). In June 1991, Dr. Heilbrun gave a presentation about "machine vision techniques" at a meeting of the American Society for Stereotactic and Functional Neurosurgery. (Tr. at 582:8 -- 584:1). n4 Dr. Heilbrun reported to that organization that he and his colleagues had demonstrated that by using standard geometric functions, "the tip of a surgical instrument within the cranium can be localized as long as the two fiduciary markers attached to the instrument can be seen simultaneously by the two video cameras." (Ex. 142 at 96). Dr. Robert Maciunas, a neurosurgeon experienced in the field of image-guided surgery, testified that optical digitizers were available in 1992. (Tr. at 1756:18-25). The most telling evidence that optical tracking was foreseeable in March 1992 is Dr. Bucholz' own statement to the Patent Office: "The emitters can be sound or light emitters." (Ex. A-8, at 74). This evidence shows that the inventor himself foresaw optical tracking at the time of the amendment.

> n4 Machine vision and optical digitizer both refer to the use of a camera system for determining the three-dimensional position of objects. (Tr. at 645:20 -- 646:23 (Heilbrun)).

[*22]

A patentee may also rebut the *Festo* presumption is by showing "that there is some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Festo, 344 F.3d at 1370* (quoting *Festo, 535 U.S. at*

741). Dr. Bucholz testified that an optical digitizer was not commercially available to him at the time he filed his patent application in October 1990, and therefore he could not have described it sufficiently in his patent application. (Tr. at 414:25 -- 415:9, 517:19 -- 518:19). This testimony does not address relevant criteria. The question is what was known to those skilled in the field of invention, not when Dr. Bucholz could obtain an optical digitizer "off the shelf." Dr. Maciunas said that optical technology was available but expensive in 1990, and in 1992 its price was coming down. (Tr. at 1756:17-25). Dr. James Duncan testified that optical position sensing had been used in medical applications before the filing date of the Bucholz *454 patent*. (Tr. at 2214:18 -- 2215:5, *see* Ex. C-18). Moreover, Dr. Bucholz' testimony about commercial availability does not address [*23] the relevant date, which is the time of the amendment. Dr Bucholz testified that "shortly after we did our first cases with this [acoustic] device an optical digitizer became available." (Tr. at 397:5-6). According to his own testimony, those cases were done during 1991, (Tr. at 398:17-19), before the date of the amendment.

Medtronic characterizes the optical technology of BrainLAB's products as an improvement or enhancement that resulted from after-arising technology. The evidence does not support that characterization. There was sufficient knowledge of optical tracking technology when Dr. Bucholz amended his patent application in 1992 for it have been described. n5

> n5 Mr. Morander, the founder of Qualisys, testifying by deposition, said that Qualisys marketed passive marker technology beginning in 1989, and that he had been using active optical marker technology since 1972. (Tr. at 885:5-15).

[HN9] The plaintiff may also rebut the *Festo* presumption by showing that "the reason for the narrowing amendment was [*24] peripheral, or not directly relevant, to the alleged equivalent." *Festo, 344 F.3d at 1369*. This inquiry focuses on "the patentee's objectively apparent reason for the narrowing amendment." *Id.*

Because the claims were vague, the patent examiner advised that "further structure should be added to the claims." (Ex. A at 57). The examiner required Dr. Bucholz to set forth the relationship between the probe and the reference points and how they interrelate. In response, Dr. Bucholz added the term "reference means" to the claim, and explained that his invention has a reference means and emitters on the probe and the patient for determining the position of the probe relative to the patient.

The prosecution history and the evidence at trial showed that by the time of the amendment Dr. Bucholz knew that the concept underlying the acoustic tracking system disclosed in his patent application could be applied to one having optical components. Dr. Bucholz told the examiner that the emitters of his system could be light emitters, but he did not claim an array of cameras or any light sensors to use light emissions in localization of instrument during tracking. The amendment [*25] cannot be deemed tangential where the added language serves to define the claim and the applicant, at the time of the amendment, could have drafted a claim that would have literally encompassed what is claimed to be the equivalent.

The burden was on Medtronic to show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent. Medtronic did not satisfy its burden.

Because the jury's finding of infringement of the Bucholz patent was based on the doctrine of equivalence and the court has now concluded that, as a matter of law that prosecution history prevents application of that doctrine in this case, that verdict must be set aside. The *rule 50(a)* motion should have been granted before the case was submitted to the jury.

Even if Medtronic were not precluded from invoking the doctrine of equivalents by prosecution history estoppel, the verdict should be set aside because the record does not support a finding of equivalence.

BrainLAB moved for judgment under *Fed. R. Civ. P. 50(b)*, renewing arguments made under *Rule 50(a)* motions [*26] before submission to the jury and in motions for summary judgment before trial. [HN10] BrainLAB's burden under *Rule 50(b)* is to show that the "jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)* (quoting *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984))*. "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp., 732 F.2d at 893* (citations omitted). In reviewing a motion under *Rule 50(b)*, "the trial court must consider all the evidence in a light most favorable to the non-mover, must draw reasonable inferences favorable to the non-mover, must not determine the credibility of witnesses, and must not substitute its choice for that of the jury between conflicting elements in the evidence." *Id.* (citations omitted). The motion should be granted only

when the court [*27] is convinced that reasonable persons could not have arrived at the conclusion reached by the jury, based upon the evidence before it. *Id.*

The Bucholz *454 patent*, entitled "System for Indicating the Position of a Surgical Probe Within a Head on an Image of the Head. (Ex. 7) was the centerpiece of Medtronic's case at trial. n6

Claim 14 reads:

> A method for indicating a position of a tip of a surgical probe which is positioned within a body of a patient on images of the body wherein the body and the images of the body include reference images corresponding to reference points in a position on the body, said method comprising the steps of:
>
> determining the position of the tip of the surgical probe relative to a reference means having a location outside the body;
>
> determining the position of the reference points of the body relative to the reference means so that the position of the tip relative to the reference points of the body is a known position;
>
> translating the known position of the tip of the surgical probe to provide a translated position within a coordinate system corresponding to the images of the body; and
>
> displaying an image of the body which [*28] corresponds to the translated position of the tip of the surgical probe.

(Ex. 7, Bucholz patent, col. 10, ll. 28-52).

> n6 The original complaint, brought by Surgical Navigation Technologies, Inc. and Sofamor Danek Group, Inc. on May 12, 1998, claimed infringement of only the Bucholz *454 patent*. Those plaintiffs did not at that time own any interest in the Roberts *056 patent* or the Heilbrun patents. Claims for infringement of the Heilbrun and the Roberts patents were added in the Third and Fourth Amended Complaints.

The court construed the term "reference means" in claim 14 of the Bucholz *454 patent* to mean an array of microphones. None of the accused products has an array of microphones. BrainLAB's VectorVison products have a pair of cameras with infrared light emitting diodes arranged around the cameras. During a surgical procedure, the light emitting diodes illuminate the operating area with infrared light. Surgical instruments, such as a probe, are equipped with reflective marker spheres. A special [*29] tool with reflective marker spheres, known as a Mayfield star, is also attached to the patient. The pair of cameras detect infrared light reflected by the markers spheres. That information is digitized and a computer performs the mathematical functions to determine the three-dimensional positions of the surgical instrument and the patient. The computer correlates those positions with images of the patient showing the target of the surgery. The images typically would be pre-operative scans of the patient obtained by imaging techniques such as computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET). n7

> n7 *United States Patent No. 6,351,659*, entitled "Neuro-navigation System," was issued to BrainLAB on February 26, 2002. (Ex. M-10). The Bucholz *454 patent*, the Roberts *056 patent*, and the Heilbrun *101* and *318 patents* are cited as prior art in the BrianLAB *659 patent*.

At trial Medtronic argued that the cameras of the BrainLAB products are equivalent to the microphone [*30] array of claim 14 of the Bucholz *454 patent*, and that BrainLAB's optical tracking system is equivalent to the method of that claim. The jury was presented with evidence comparing surgical navigation systems having acoustic tracking units and those having optical tracking units, which were described as either "active" or "passive." In an acoustic system, the surgical probe is equipped with sonic emitters, typically spark gap emitters. (Ex. 90, Richard D. Bucholz, M.D. and Kurt R. Smith, D.Sc., *A Comparison of Sonic Digitizers versus Light Emitting Diode-based Localization*, in INTERACTIVE IMAGE-GUIDED SURGERY, 179-200 (Robert J. Maciunas, M.D., ed., American Association of Neurological Surgeons 1993) (Ex. 533)). Position is determined by measuring the time of flight of sound from the emitters to an array of microphones. "By comparing the time needed for the sound to arrive at each microphone, the position of the sound emitters can be determined." (Ex. 90 at 183; Tr. at 1692:19 -- 1694:6 (Maciunas)). In an active optical system, light-emitting diodes on the surgical instruments flash and emit light that is detected by a camera array. (Ex. 90 at 191; Tr. at 283:6-19 (Smith); 885: [*31] 18-24 (Morander);Tr. at

1703:3-13 (Maciunas)). The accused BrainLAB products have optical tracking units with cameras, but the markers on the surgical tools are reflective spheres rather than light-emitting diodes. The markers themselves are not energized to emit a signal. Instead they reflect light emitted by infrared light emitting diodes arranged around the cameras. These markers are referred to as "passive" markers. (Tr. at 885:25 -- 886:3 (Morander)).

Medtronic argues that the Bucholz *454 patent* is a pioneering patent entitled to a broad range of equivalents. [HN11] "No objective legal test separates pioneers from non-pioneers," *Augustine Med., Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1301 (Fed. Cir. 1999)*, but one indicia of a pioneer is a lack of "extensive prior art to confine and cabin their claims." *Id.* The Bucholz patent cites 59 patents and 23 other publications as references. The testimony of Medtronic's witnesses stating that Medtronic's *StealthStation* product revolutionized surgery does not establish that *the Bucholz patent* is a pioneering patent entitled to an especially broad range of equivalents. None of the plaintiffs has ever marketed a [*32] surgical navigation product that practices claim 14 of the Bucholz patent. The StealthStation product goes well beyond Claim 14 of the Bucholz patent. As Dr. Bucholz testified, "the StealthStation does embody the concept in my patent." (Tr. at 381:4-19). Employing concepts is not practicing the elements of the claim. As will be seen, the demonstration of the StealthStation was error and appears to have contributed to jury confusion at trial.

[HN12] "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo, 535 U.S. at 733*. Insubstantiality may be shown by the function/way/result or "triple identity" test. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39-40, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997)*. That test focuses on the function served by a particular claim element, the way that element serves that function, and the result obtained by that element. *Id.* "The doctrine of equivalence must be applied to individual elements of the claim, not to the invention as a whole." *Id. at 29*.

Dr. Eric Grimson, testifying [*33] as an expert on behalf of Medtronic, stated that the function of the array of microphones in the claimed invention is to track the position of an object. (Tr. at 746:5 -- 747:6). Dr. Kurt Smith described that function as well. (Tr. at 368:1-6). The evidence showed that the cameras of the accused products perform substantially the same function of locating the position of a markers on a surgical instrument and a patient in an operating room. (Tr. at 744:21 -- 748:12; 751:1-23; 759:14 -- 760:1; 2431:5 -- 2432:19 (Grimson); Ex. 73 (Northern Digital, Inc.'s Polaris Optical Tracking System Manual); Ex. 75 (1992 Qualisys Manual)).

With respect to result, Dr. Grimson testified that the result of the microphone array in an acoustic system is to acquire a set of 3D coordinates. (Tr. at 746:25 -- 747:6; 749:17-22). Dr. Bucholz testified that an acoustic tracking unit and an optical system tracking unit both provide the three-dimensional coordinates of the markers to the navigation computer, so that the computer can correlate the positions of the patient to images of the patient. (Tr. at 411:16 -- 412:5). Dr. Smith, one of the founders of Surgical Navigation Technologies, Inc., testified that [*34] acoustic and optical tracking units achieve the same result. (Tr. at 368:13-18). The testimony of Dr. Grimson and the documents he relied upon in forming his opinion showed that the cameras of the accused products provide the navigation computer with the coordinate positions of marked objects so that the positions can be correlated to images of the patient. (Tr. at 749:7 -- 748:12; 2432:20 -- 2433:17).

According to Medtronic, the way prong of the tripartite test is satisfied by testimony and documentary evidence showing that both acoustic and optical tracking units detect radiation (energy waves) via sensors, and use triangulation to compute the three-dimensional position of objects. Summarizing this evidence during closing argument, Medtronic's counsel argued to the jury that "tracking is tracking." (Tr. at 2852:2 -- 2853:2; 2996:5).

Upon review of the testimony and documentary evidence, the court finds and concludes that the jury's finding that the accused products infringe claim 14 of the Bucholz *454 patent* was not supported by the evidence and resulted from plaintiffs' deliberate distortion of the court's claim construction rulings. The meaning of numerous claim terms were disputed [*35] during the claim construction phase. There were disputes about four terms in claims of the Roberts *056 patent*, eight terms in claims of the Bucholz *454 patent* and a related patent, and nine terms in claims of the Heilbrun *101* and *318 patents* and a related Heilbrun patent. These issues were briefed extensively, and the parties submitted documentary evidence, declarations, deposition testimony, and tutorial videos about the field of image-guided surgery. The court held oral argument and issued its rulings on September 29, 2004. During the claim construction phase, Medtronic advocated that the term "reference means" is not means-plus-function language and should be interpreted to mean "one or more sensors or receivers." The court interpreted this term to mean an array of microphones.

At trial Medtronic's counsel ignored the limitations of the Bucholz claim made by this court and misdirected the jury to adopt a different reading of the claim lan-

guage. Its first witness, Dr. Smith, testified that the invention of the Bucholz patent was one having "sensors" to detect "radiation." (Tr. at 260:9 -- 261:2). Medtronic's expert witness, Dr. Grimson, also explained his application of the [*36] function/way/result test by referring to the claimed microphone array as "sensors" for detecting "radiation or energy waves." During closing argument, Medtronic's counsel argued to the jury that the plaintiffs' broad view of the claim was supported by the illustrations in the patent and the language of the specification. (Tr. at 2982 -- 2984).

Medtronic's disagreement with the court's claim construction does not give counsel license to mislead the jury by their presentation of evidence and argument. The construction urged by plaintiffs' witnesses and counsel would have made the Bucholz claim 14 vague and indefinite as the examiner found before the limiting amendment was made. In his rebuttal argument, counsel told the jury that BrainLAB had admitted equivalence in its FDA submission. Tr. at 2976:4 -- 22). That statement was an abuse of advocacy. The jury was asked to make a product-to-product comparison despite the court's efforts to explain that the claims must be compared to the defendants' accused product. The strategy appears to have been successful and the demonstration of the StealthStation was used to make that argument persuasive, contrary to the court's instructions.

When [*37] proper comparison is made the evidence does not show that the way aspect of the function/way/result test has been satisfied. Contrary to Medtronic's argument, evidence showing that the accused products and claimed invention rely on the same underlying principle of triangulation does not establish equivalence. That fact that acoustic and optical systems both have components that sense signals from the object to be located is a conceptual similarity, but not the insubstantial difference required for infringement under the doctrine of equivalents. *See Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1534 (Fed. Cir. 1987)* (stating that no claim may be drawn to a "concept."). To satisfy the "way" aspect of the function/way/result as advocated by Medtronic would distort the doctrine of equivalence. [HN13] The doctrine of equivalence "is designed to do equity . . . it is not designed . . . to permit a claim expansion that would encompass more than an insubstantial change." *Perkin-Elmer Corp., 822 F.2d at 1532.*

Putting aside the comparison showing that the acoustic tracking of the claimed invention and the passive optical tracking units of the accused [*38] products both have sensors and rely on triangulation, the remaining evidence does not support the jury's conclusion of equivalence. The microphones of an acoustic system are used to measure the time of flight of sound. In an optical system, the cameras detect spots of light. The evidence clearly showed that those differences are significant in the context of surgery in an operating room. The accuracy of an acoustic system depends on the speed of sound remaining constant as the sound travels from the emitter to the microphone array. With an acoustic system, echoes and variables such as temperature fluctuation can cause errors in detecting the positions of objects. (Ex. 90 at 183). In their 1993 article, Dr. Bucholz and Dr. Smith recognized drawbacks associated with acoustic tracking in an operating room. (*Id.*, at 183, 194-96). With respect to the echo problem, they stated in their article, "If the delayed echo is used for localization, the resultant positional error is extreme. This effect can be corrected by slowing down the firing rate of the emitters and allowing all echoes to die out before the emitters are reactivated." (*Id.*). Echoes are not an issue with optical tracking. [*39] Furthermore, in an acoustic system, the several emitters used to locate the probe and the patient must be activated separately and the microphone array detects them sequentially. (Tr. at 1693:11-23 (Maciunas); Tr. at 2223:1-16 (Duncan)). In the passive optical tracking units of the accused products, the light reflected from multiple markers can be detected simultaneously, thus permitting simultaneous detection of instruments. (Tr. at 2223:9-16 (Duncan)). Acoustic tracking requires that the surgical probe have a power source because the sonic emitters must be energized. (Ex. 7, the *454 patent* at col. 7, ll. 62-64 ("The surgical probe 302 . . . has a bundle of wires 364 attached thereto"); Tr. at 1694:2-6 (Maciunas)). The reflective markers of the BrainLAB products are unencumbered by wires or batteries. (Tr. at 1710:1-8 (Maciunas)).

Dr. Bucholz used his sonic system to perform approximately eleven or twelve operations on patients, mainly during 1991. (Tr. at 398:15-19; 428:10-14). Dr. Smith acknowledged that his company Stealth Technologies (later known as Surgical Navigation Technologies, Inc., and then Medtronic Navigation Technologies, Inc.) never commercialized a surgical navigation [*40] system with an acoustic tracking unit. (Tr. at 322:1-12). Dr. Smith said that Stealth Technologies determined that a sonic system was not suitable after he and Dr. Bucholz performed a study comparing sonic localizers and light-emitting diode based localizers. (Tr. at 322:17 -- 323:6). Dr. Roberts testified that he had performed approximately 100 surgeries with a sonic digitizing microscope over a ten year period and that others used sonic systems in clinical settings in the late 1980s through the early 1990s (Tr. at 699:6 -- 700:6), but there was no evidence of such systems being commonly used by practicing surgeons. Dr. Duncan testified that acoustic systems were never fully adopted by the image guided surgery community. (Tr. at 2224:3-6). No company presently sells an

surgical navigation system with an acoustic tracking unit. (Tr. at 1756:7-8 (Maciunas); 2224:3-14 (Duncan)).

The question is not whether surgical instruments having active optical markers are equivalent to surgical instruments having passive optical markers. The proper comparison is between acoustic tracking and the passive optical tracking units of the accused products as used during surgery. The evidence shows that [*41] an array of microphones and a pair of cameras can both be used to locate the X, Y, Z coordinates of markers on a surgical probe and a patient, but they don't perform that function in a substantially similar way. The evidence does not support a finding that determining the three-dimensional position of an object by detecting spots of light is insubstantially different from determining the three-dimensional position of an object by measuring the time-flight of sequentially emitted sounds. Eyes and ears are different. The use of cameras to detect reflected light represents more than a minor improvement or slight change in technique over a system having a microphone array for detecting sonic signals. These are substantially different systems for surgical navigation.

Medtronic argues that testimony of Dr. Smith, Dr. Bucholz, Dr. David Roberts, and Dr. Grimson shows that acoustic and optical tracking units can be modularly substituted and thus are interchangeable and equivalent. This testimony and the other evidence cited by Medtronic to support this point show only that surgical navigation systems having acoustic and optical tracking units both can be used to obtain three-dimensional coordinates [*42] of objects. [HN14] "That persons skilled in the art would have known of the interchangeability of claimed with unclaimed elements is a factor in considering equivalence . . ., yet the accused devices must still perform substantially the same way to obtain the same result." *Perkin-Elmer Corp., 822 F.2d at 1535* (internal citations omitted).

For these reasons, the jury's verdict of infringement of the Bucholz *454 patent* must be set aside.

The defendants' motion for judgment as a matter of law that defendants do not infringe the Roberts 056 patent

The jury found that the microscope integration feature of BrainLAB's VectorVision, Kolibri, and BrainSuite products infringes the Roberts *056 patent*. That patent is entitled "Reference Display Systems for Superimposing a Tomographic Image Onto the Focal Plane of an Operating Microscope." (Ex. 19). Its filing date is February 18, 1986. The patent generally covers a computer-based surgical navigation system that allows a surgeon to look through the eyepieces of a microscope at a target area and see, for example, the outline of a diseased body part (*e.g.*, a tumor) superimposed on a live image of the patient's body part ([*43] *e.g.*, the brain).

Medtronic claimed infringement of Claim 1 of the Roberts *056 patent*. Claim 1, an independent method claim, reads:

> A method of integrating image information from an imaging device and an operating microscope during an operative procedure on body parts of a patient comprising:
>
> positioning an operating microscope in the course of said operative procedure at an operative location relative to the patient;
>
> establishing the spatial relationship among the image information, the patient, and the focal plane of the microscope;
>
> introducing the image information and spatial relationship to a computer and reformatting the image information to generate a computer-generated image of the body part at a determined plane related to the focal plane of the microscope; and
>
> projecting the computer-generated image into the optics of the operating microscope for coordinated viewing of the computer-generated image and the patient.

(the Roberts *056 patent*, col.175, ll. 13-31).

There was no dispute at trial that the accused products perform the first, third and fourth steps of the claimed method. The issue was whether the accused BrainLAB products [*44] perform the second step by equivalents. The jury was instructed as follows:

> Establishing the spatial relationship among the image information, the patient and the focal plane of the microscope means determining the relative position of objects to each other using a position and orientation measurement system, including an acoustic reference system or an electromagnetic reference system. As written, the claim does not include use of an optical reference system.

(Rulings on Claim Construction Issues, Sept. 29, 2004). n8

> n8 "Reference system" is the terminology of the Roberts *056 patent*. In Figure 1 of the patent, item 11 is labeled "reference system."

The determination of equivalence requires comparison of BrainLAB's passive optical tracking system to the acoustic and electromagnetic reference systems disclosed in the Roberts patent. In the Roberts patent, an acoustic reference system is illustrated in Figure 2 and described at column 6, line 48 to column 11, line 17. As described above, such a [*45] system uses an array of microphones positioned over the surgical field. Sonic emitters are used to locate points on the patient correlating with points on images of the patient. Sonic emitters associated with the microscope are used to track the position of the microscope, so that the position of objects in the operating room can be correlated to the image information. This process is explained in Exhibit 91, an article entitled *The Sonic Digitizing Microscope*, co-authored by Dr. Roberts:

> . . . At the start of the surgical procedure, spatial registration of the imaging studies with the head (secured in three-point pin fixation, as in conventional practice) is accomplished by holding a spark gap over each of three fiducial points that have also been identified during previous imaging through visualization of an overlying marker. The transformation between OR [operating room] space and image space is determined from this information.
>
> Subsequent monitoring of the position and orientation of the operating microscope array is enabled by a sterilized bracket containing three spark gaps, which is attached to the microscope at the level of the objective lens. . . . . The OR [*46] coordinate system is based upon the microphone array. . . . The relationship between image coordinate space and that of the microphone array is defined by the transformation determined by knowing the coordinates of the same fiducial points in both coordinate systems.

(David W. Roberts, M.D., Eric M. Friets, B.S., John W. Strohbehn, PhD., & Taku Nakajima, M.D., *The Sonic Digitizing Microscope, in* INTERACTIVE IMAGE-GUIDED SURGERY 106-07 (Robert J. Maciunas, M.D., ed., American Association of Neurological Surgeons 1993) (Ex. 533); Tr. at 697:8 -- 698:19 (Roberts)).

The specification of the Roberts *056 patent* also discloses an electromagnetic reference system. (Roberts *056 patent*, col 11, l. 18 -- col. 12, l. 33; Figs. 6A, 6B, and 6C). "The basic principle behind this system is to measure the back EMF (electromotive force) created in a coil 51 by a magnetic field generated by a source coil 50." (Roberts *056 patent*, col. 11, ll. 23-25). The specification states:

> To uniquely determine the position and orientation of the receiver system, three source coils 50A, 50B, and 50C must be used, as shown in Fig. 6C. To determine the position and orientation of the receiver [*47] with respect to the source, the following procedure is used. First, an alternating current source I[s1] is generated and three receiving voltages (V[R1 1], V[R2 1], V[R3 1]) are measured and recorded. The first current is then turned off, and the second source current, IS2 is turned on. This current generates the three voltages (V[R1 2, V[R2 2, V[R3 2]) which are measured and recorded. Current I[S2 is then turned off, and current I[S3] turned on, and the voltages (V[R1 3], V[R2 3], V[R3 3]) are then measured and recorded. From the knowledge of the three currents . . . and the nine voltages . . ., plus the number of turns for each coil and its physical dimensions, and a basic knowledge of physics, the position and orientation of the sensor coil and the receiving coil can be uniquely determined. An electromagnetic supply 53 furnishes current to the coil 50 (or 50A, 50B, and 50C) and a signal processing circuit 54 measures V[R1] . . .; outputs of the processor 54 are connected to the computer 6.

(Roberts *056 patent*, col. 12, ll. 6-33; *see also* Tr. at 839:14 -- 840:7 (Grimson)).

Dr. David Roberts, one of the named inventors, explained that in his patent [*48] a reference system is a tracking system. He testified that it is the component of the system that locates where the patient's head is in the operating room, and locates where the operating microscope is in the operating room. (Tr. at 693:21 -- 694:3). Dr. Grimson, testifying as an expert on behalf of Medtronic, stated that the accused products perform the same tracking function. (Tr. at 2431-32). There was substantial testimony and documentary evidence confirming that the passive optical tracking units of BrainLAB's products perform that function.

With respect to result, the jury heard evidence that both acoustic and optical tracking units provide 3-dimensional coordinates (X, Y, Z positions of markers) to the navigation computer. This evidence was presented through the testimony of Dr. Grimson, Dr. Bucholz, Dr. Smith, and Dr. Roberts. Additionally, Dr. Grimson testified that the BrainLAB software code shows that the coordinate information provided by the cameras of the BrainLAB system is used to perform computations that establish the spatial relationship among the image information, the patient, and the focal plane of the microscope. (Tr. at 795:10 -- 802:7). Dr. Grimson stated, [*49] "This computation, in particular the execution of these matrix operations, is basically determining that transformation." (Tr. at 799:24 -- 800:3).

The question then is whether the way prong of function/way/result test is met by evidence showing that acoustic, electromagnetic, and optical tracking units all use energy waves to determine the three-dimensional position of objects, using triangulation. Dr. Roberts testified as follows:

> Q (by Ms. Elson): And, just generally, how did they -- what was the way in which they performed that tracking?
>
> A (by Dr. Roberts): Although the type of energy that they use could be seemingly very different to look at, that energy simply went into the box of the reference system, the output of which was a digitized piece of information, specifically the spatial coordinates of the object being tracked.

(Tr. at 696:10-16).

For the reasons discussed above with respect to the Bucholz patent, the "way" aspect of the function/way/result test is not met by describing acoustic, optical, and electro-magnetic tracking systems as having a common denominator, the use of waves of energy to determine the three-dimensional position of objects, by [*50] triangulation. That broad conceptual similarity does not support a finding of equivalence. Medtronic presented no specific testimony comparing the disclosed electromagnetic reference system to the passive optical system of the accused products. For the reasons already discussed with respect to the Bucholz patent, the differences in the performance of an acoustic tracking system and the passive optical system of BrainLAB's products are not insubstantial. Medtronic failed to show that those differences would not also be significant and substantial in the use of an electromagnetic tracking system.

Because Medtronic's evidence does not support the finding that the accused products infringe claim 1 of the Roberts *056 patent*, BrainLAB's argument that infringement is precluded under the doctrine of disclosure dedication need not be addressed. The verdict of infringement of the Roberts *056 patent* by the DOE must be set aside.

The defendants' motion for judgment as a matter of law that defendants do not infringe the Heilbrun 101 and 318 patents

The jury also found infringement of the Heilbrun *101 patent* and the Heilbrun *318 patent*. The Heilbrun patents have a common title, "Apparatus [*51] and Method for Photogrammetric Surgical Localization." They derive from a common parent application filed on April 12, 1992. Claim 1 of the *101 patent*, an independent apparatus claim, reads:

> Apparatus for defining a location of a medical instrument relative to features of a medical workspace including a patient's body region, comprising:
>
> workspace imaging means positionable for producing a plurality of pairs of images of the medical workspace, each of said pairs comprising two images made along one of each of a different one of two sightlines, said sightlines intersecting at an angle;
>
> digitizing means operably disposed for digitizing each of said images of said image pairs to produce sets of digital image

> signals, one said set of digital image signals corresponding to each of said images;
>
> fiducial means removably positionable in said workspace for providing a series of fiducial points held in fixed spatial relation to one another, and computing means connected to said digitizing means to receive said digital image signals therefrom, said computing means being operable to:
>
> > establish a workspace coordinate framework in three dimensions from a first selected [*52] one of said pairs of images made when said fiducial means is positioned within said workspace,
> >
> > determine workspace coordinates in said workspace coordinate framework of any selected point which can be identified from both images of said first selected image pair,
> >
> > receive a set of scan coordinates for each of three or more selected landmarks present in a scan made in a scan coordinate framework, and correlate said scan coordinates with the workspace coordinates of said landmarks as derived from one of said image pairs, said landmarks being selected from the group of anatomic features, surgical implants, and radiologic implants,
> >
> > compute conversion functions for converting the scan coordinates of a selected feature in said scan to corresponding workspace coordinates in said workspace framework, and for converting observed workspace coordinates of a selected feature observable in both of said images of a selected one of said image pairs to corresponding scan coordinates in said scan coordinate framework, and
> >
> > perform said conversion functions for user-selected features found in said scan or in a subsequent selected one of said image pairs.

(Ex. 1, Heilbrun [*53] *101 patent*, col. 14, ll. 4-51). Claim 1 of the *318 patent*, also an independent apparatus claim, reads the same as claim 1 of the Heilbrun *101 patent*, except that the "computing means" includes the following:

> . . . memory structure having pattern recognition data and instrument structure data Stored therein, said pattern recognition data and said instrument structure data both being correlated to individual ones of a plurality of different medical instruments . . .

(Ex. 3, Heilbrun *318 patent*, col. 15, ll. 40-44).

The Heilbrun patents claims include cameras ("workspace imaging means") for locating objects within a medical workspace. The distinctions relevant to whether BrainLAB's products infringe the Bucholz *454* and the Roberts *056 patents* -- *i.e.*, the differences between acoustic and passive optical tracking -- are not relevant to the Heilbrun patents. The parties' dispute about infringement of the Heilbrun patents focused on whether BrainLAB's VectorVision products include "computing means being operable to establish a workspace coordinate framework in three dimensions from a first selected one of said pairs of images *made when said fiducial means is* [*54] *positioned within said workspace*." (emphasis added).

The jury was instructed that "computing means" is a means-plus-function term and that establishing a workspace coordinate framework in three dimensions is one of the functions of the computing means. The jury was instructed:

> Workspace coordinate framework is a static or immovable coordinate system centered in the workspace that must be re-

> established if one or more of the cameras are moved.

The jury instructions also stated that:

> The computing means comprises a central processing unit, memory, a data input, an image processing unit, a data output for outputting a display signal, and hardware or software for computing a three-dimensional workspace coordinate framework from the digitized images of the fiducial means, and equivalent structure.

"Fiducial means" is also a means-plus-function term. The jury was instructed as follows:

> The function of the fiducial means is providing a series of fiducial points held in a fixed spatial relationship to one another. It is an arrangement of reference points held in a fixed spatial relation to one another by a support structure or equivalents thereof, [*55] or an arrangement of reference points projected by a light projector, and equivalents thereof. The minimum number of points is determined by the particular projection algorithm employed.

These instructions correspond with the Rulings on Claim Construction Issues of September 29, 2004.

Literal Infringement of the Heilbrun patents by BrainLAB's VectorVision products

[HN15] Determining whether a means-plus-function claim limitation is met literally requires comparison of function and a comparison of the accused structure with the structure disclosed in the patent for performing the recited function. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308 (Fed. Cir. 1998)*. ("To determine whether a claim limitation is met literally, when expressed as a means for performing a stated function, the court must compare the accused structure *with the disclosed structure* and must find equivalent *structure* as well as *identity* of claimed *function* for that structure." (citation omitted, emphasis in original)). The jury found that BrainLAB's VectorVision products literally infringe the Heilbrun patents. To reach that result, the [*56] jury must have determined that BrainLAB's VectorVision products perform the function of "establishing a workspace coordinate framework in three dimensions . . ." with the same or equivalent structure to that disclosed in the patent.

Dr. Russell Taylor, Medtronic's expert witness, opined that BrainLAB's VectorVision products literally infringe the Heilbrun patents. Dr. Taylor said that the VectorVision's Mayfield reference star is the "fiducial means" used by the VectorVision's computing system to establish a workspace coordinate framework. (Tr. at 953:9 -- 953:18). The Mayfield reference star is a device that holds an array of three marker balls in a fixed relation to each other. (Tr. at 953:11-13 (Taylor)). The Mayfield star remains attached to the patient during surgery. When a VectorVision system is used to perform cranial surgery, the Mayfield star is attached to a frame that secures the patient's head firmly to the operating table. (Tr. at 942:1-7 (Taylor)). When a VectorVision system is used for spinal surgery, a similar frame is attached to the patient's spine. (Tr. at 1067:20 -- 1068:13 (Taylor); 1964:7-14 (Mackey)). Surgical navigation with a VectorVision system cannot proceed [*57] without the use of the Mayfield star. (Tr. at 2105:5 -- 2106:15 (Freilinghaus)).

In the Heilbrun patents, establishing a workspace coordinate framework is a function distinct from determining the location of an object within that framework. After the computing means has established the workspace coordinate framework, the computing means can then "determine *workspace coordinates in said workspace coordinate framework* of any selected point which can be identified from both images of said first selected image pair." (Ex. 1, Heilbrun *101 patent*, col. 14, ll. 27-30 (emphasis added)). The specification states, "Once the workspace coordinate framework has been computed, computing means 232 is further operable to compute the 3D location coordinates within the framework of any feature of interest whose position may be observed by means of the images made with both of cameras 200, 202." (*Id.*, col. 6, ll. 58-68). Objects of interest include fiducial markers placed on the patient, anatomical features of the patient, and/or markers on medical instruments and devices. (*Id.*, col. 7, ll. 1-17). In the Heilbrun patents, the workspace coordinate framework is established with the fiducial [*58] means *before* the 3D position of other objects in the workspace, such as markers on a surgical probe, can be located. The specification states, "A projection algorithm is applied to reconstruct a workspace 3D coordinate framework from the calibration image pair." (Ex. 1, col. 4, ll. 29-31).

Dr. Taylor acknowledged that in forming his opinion, he assumed that the VectorVision system finds the Mayfield star first and computes a workspace coordinate

framework before it determines the location of other objects within that framework. (Tr. at 1118:17 -- 1119:5). He could not confirm that his assumption was correct. (Tr. at 1124:12-16).

Dr. Johannes Manus, a BrainLAB employee who oversees BrainLAB's image-guided surgery software, testified that BrainLAB's VectorVision system does not detect the Mayfield star first:

> Q: Now, the Mayfield reference star is not the first thing that it --
>
> A: No.
>
> Q: -- identifies?
>
> A. No, the Mayfield reference star, I think, is the third one in this list.
>
> Q: So the software in the VectorVision does not look for the Mayfield reference star first and then track the instrument relative to it.
>
> A: No, it first detects all -- it [*59] starts with the ultrasound adapter, with the microscope adapter, and so on, and that's it.
>
> Q: So if the reference star moves, does that affect in any way the values that the cameras send back to the VectorVision system?
>
> A: No, the values of markers are always sent in the coordinate system of the camera system.

(Tr. at 2062:14 -- 2063:5). Mr. Nils Frielinghaus, reaffirmed that the Mayfield reference star is not detected first. He testified as follows:

> Q: All right. Now, what instrument does the VectorVision<2> software look for first?
>
> A: It first looks for the ultrasound star, then the microscope, then some stars which are rarely used, then there's the reference star, additional instrument adapters, and the pointer is the last it detects.
>
> Q: Now, how do you know that's the order that it uses?
>
> A: There is a list in the software that defines the order.

(Tr. at 2087:24 -- 2088:12).

Medtronic contends that the order in which the VectorVision system locates surgical tools and the Mayfield star is irrelevant because the claim is an apparatus claim, rather than a method claim. This argument ignores the claim language requiring that a 3D workspace [*60] coordinate framework be in place before the workspace coordinates of selected points are determined.

The crux of the parties disagreement about the role of the Mayfield star is whether the function of establishing "a workspace coordinate framework in three dimensions from a first selected one of said pairs of images made when said fiducial means is positioned within said workspace" is a function that includes using the fiducial means for calibrating the cameras. Establishing a three-dimensional coordinate system involves computing three-dimensional coordinates from two-dimensional positions. The relative position of the two cameras to each other is one of the measurements that must be known to compute three-dimensional coordinates from two-dimensional positions. (Ex. 111 at BrainLAB 2261, Tr. at 1053:16-19; 1116:12 (Taylor)). The specification of the Heilbrun patents describes a calibration process done by photographing the fiducial means in the workspace from two different camera positions. (Ex. 1, Heilbrun *101 patent*, col. 3, ll. 32-46; Tr. at 555:1-12 (Heilbrun)). The specification uses the term "calibration means" to refer to the structure that is the "fiducial means" of the [*61] claim. (Ex. 1, *101 patent*, col. 3, ll. 31-33). Dr. Heilbrun referred to this fiducial structure as a "video localizer" during his testimony. (Tr. at 593:25; 595:21-24). Dr. Heilbrun described the role of this fiducial structure stating, "we could put the fiducial structure and figure out the workspace. And if-if the cameras didn't move then you could take it out. . . ." (Tr. at 560:22-26; *see also* 595:21 -- 596:7). The role of the fiducial structure in this camera calibration process underlies the court's interpretation of "workspace coordinate framework" as a static coordinate system that must be reestablished if the cameras move.

The evidence showed that in the VectorVision system, the Mayfield star plays no role in calibrating the cameras. The VectorVision<2> uses Polaris cameras manufactured by Northern Digital, Inc. (Tr. at 947:1-6 (Taylor)). The Polaris cameras are pre-calibrated by the manufacturer, and the VectorVision<2> can locate the position of objects without the necessity of performing

camera calibration in the operating room. (Tr. at 1081:23 -- 1083:2 (Taylor)). The Vector Vision Classic uses cameras manufactured by Qualisys. (Tr. at 947:1-6). Medtronic's response [*62] to BrainLAB's motion for summary judgment describes a calibration rod used for calibrating the Qualisys cameras of the VectorVision Classic. In that response Medtronic stated, "The VV Classic establishes a workspace coordinate framework from pairs of images taken while the calibration rod is placed in the system." (Pl.'s Mem. in Opp'n to Defs.' Mot. for Summ. J. of Non-infringement of the Heilbrun Patents, at 15.). Dr. Taylor's testimony at trial did not address calibration of the Qualisys cameras with this calibration rod.

The Mayfield star serves a different function. It is used to continuously, or dynamically, track the location of the patient. (Tr. at 2059:15-18 (Manus); Tr. at 2093:19-20 (Freilinghaus)). The VectorVision system captures new images of the Mayfield star approximately 20 times a second. (Tr. at 1104:9-16 (Taylor)). The VectorVision system does this whether or not the cameras move. If the patient moves or if the cameras move, tracking continues without any recalibration of the cameras. Dr. Taylor agreed that camera movement is not a factor in this process. (Tr. at 1102:14-22).

Under cross-examination, Dr. Taylor drew a distinction between the calibration of "interior [*63] parameters," such as the focal length of the cameras and the relative position of the cameras, and the calibration of "exterior parameters" which he described as the position of the cameras relative to some kind of object and some kind of coordinate system. (Tr. at 1116:4-18). Dr. Taylor stated that "camera calibration" (*i.e.*, the acquisition of information about "interior parameters") is not necessary in the Heilbrun patent claims. (Tr. at 1137:7-10). Dr. Taylor did not provide any evidence to support this distinction.

Dr. Taylor testified that when the VectorVision system captures images of the Mayfield star, it creates a workspace coordinate framework that is static until the system sees a new value. (Tr. at 1104:1-21)). He opined that BrainLAB's VectorVision products establish a static workspace coordinate system with the Mayfield star every 1/20th of a second. (*Id.* at 1153:16 -- 1154:4). Medtronic also argues that the jury's verdict is supported by BrainLAB's own documents. Exhibit 43, a BrainLAB document describing VectorVision accessories, states:

> The Mayfield TM Reference Clamp establishes the 3D coordinate system for the VectorVision Neuronavigation System [*64] within the operating field and is identified by the IR camera system using a special geometrical arrangement of three reflective marker spheres. The pointer tool's and all additional instruments' positions in 3D space are related to this reference clamp.

(Ex. 43, "Compatibility with Accessories/Auxiliary Devices & Environmental Use," at BrainLAB 12341; *see also* Ex. 119, at BrainLAB 16488; Ex. 39 at SNT 0174133).

The evidence does not support a finding that the Mayfield star is the fiducial means used to establish a workspace coordinate framework, as those terms are used in the Heilbrun patents. The Heilbrun patents require that establishing a workspace coordinate framework includes camera calibration and the "fiducial means" must be present in the medical workspace to accomplish that function. BrainLAB's system locates objects in a coordinate system that is based on camera calibration done without use of the Mayfield star. BrainLAB's system locates objects (without reference to the Mayfield star), and then relates the location of objects to the location of the Mayfield star. The Mayfield star fixes the location of the patient in the operating room. That function is different [*65] from establishing a fixed 3D coordinate system. Relating the known 3D position of a surgical instrument to the known 3D position of the Mayfield star is not the same process as "establishing a workspace coordinate framework."

The jury's finding of literal infringement was based on Dr. Taylor's assumption as to the purpose of the Mayfield Star which is not supported by the evidence. This finding must be set aside.

Infringement of the Heilbrun patents under the Doctrine of Equivalents by BrainLAB s Vector Vision products

[HN16] A means-plus-function limitation may be present in an accused product literally or under the doctrine of equivalents. *See Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1320-21 (Fed. Cir. 1999)*. Equivalence of a means-plus-function limitation is shown by proof that the accused product contains a structure that performs an *equivalent function* to the one recited in the claim limitation. *Id. at 1320-21* ("Under *§ 112*, 6, the accused device must perform the identical function as recited in the claim element while the doctrine of equivalents may be satisfied when the function performed by the accused device is only substantially [*66] the same."). The jury's finding of infringement under the doctrine of equivalents must rest on findings that the VectorVision products perform a function equivalent to the function of "establishing a workspace coordinate framework in three dimensions from a first selected one of said pairs of images

made when said fiducial means is positioned within said workspace," and that the accused products perform that function with equivalent structure to the structure disclosed in the patents.

Medtronic's expert witness, Dr. Taylor, addressed only literal infringement. (Tr. at 1041:3-5). The record is devoid of particularized testimony to support the jury's verdict finding that the VectorVision products infringe under the doctrine of equivalents. [HN17] Expert testimony is not required to prove infringement under the doctrine of equivalents. However, the Federal Circuit has cautioned that:

> a patentee must . . . provide particularized testimony and linking argument as to the "insubstantiality of the differences" between the claimed invention and the accused device or process, or with respect to the function, way, result test when such evidence is presented to support a finding of infringement [*67] under the doctrine of equivalents. Such evidence must be presented on a limitation-by-limitation basis. *Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice.* (emphasis added).

Network Commerce, Inc. v. Microsoft Corp., 422 F.3d 1353, 1363 (Fed. Cir. 2005) (quoting *Tex. Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996)*); *see also Lear Siegler, Inc. v. Sealy Mattress Co., 873 F.2d 1422, 1425 (Fed. Cir. 1989)* ("The evidence and argument on the doctrine of equivalents cannot merely be subsumed in plaintiff's case of literal infringement.").

Medtronic provided no evidence from which the jury could determine that the differences between the claimed invention and the accused products are insubstantial as to any element or limitation not literally present in the accused products. Dr. Taylor's testimony about the functionality of BrainLAB's VectorVision system is not sufficient to show infringement under the doctrine of equivalents. The "linking argument" of Medtronic's counsel does not fill the gap. The jury's finding [*68] of infringement under the doctrine of equivalents is without evidentiary support.

Literal Infringement of the Heilbrun 101 patent by BrainLAB s ExacTrac product

The jury found that BrainLAB's ExacTrac product infringes the Heilbrun *101 patent*, both literally and by equivalents. BrainLAB's ExacTrac product is a radiation therapy system. The ExacTrac product and components are pictured and described in Exhibit 307, the Clinical User Guide for BrainLAB's Novalis Body/ExacTrac system. Like the VectorVision surgical navigation system, the ExacTrac is a computerized system that uses two infrared cameras for imaging the workspace and passive markers for locating objects within the workspace. (Ex 104; Ex. 307, at BrainLAB 112933).

The ExacTrac system works with a radiation machine, known as a linear accelerator or Linac. The Linac is stationary in the radiation therapy room. The ExacTrac system aligns a patient on a couch to a precise location in relation to the "isocenter" n9 of the Linac, so that the radiation ray precisely targets the portion of the patient's body to be treated. The isocenter of the Linac is the medical instrument of the system.

> n9 This word was not defined in the evidence. Presumably it means the exact center of the beam of radiation.

[*69]

The pair of infrared cameras acquire the 2D positions of reflective markers for the purpose of 3D tracking. (Ex. 303, at BrainLAB 94766). These cameras are affixed to the ceiling of the radiation therapy room. (Ex. 307, at BrainLAB 112933). Reflective markers affixed to the patient, and other tools with reflective markers, are used for positioning the patient. (*Id.* at BrainLAB 112994; Tr. at 1005:12-15). Various calibration tools also have reflective markers. (Ex. 307, at BrainLAB 112938-55).

BrainLAB's user guide shows that the ExacTrac system is based on a fixed three-dimensional coordinate system having the Linac's isocenter as the point of origin. (*Id.* at BrainLAB 112933). The user guide describes a number of calibration steps that must be done in preparation for treating a patient with the ExacTrac system. (*Id.* at BrainLAB 112935-61). One calibration step described in the User Guide is referred to as "isocenter calibration." The Clinical User Guide states, "The isocenter calibration aligns Novalis Body/Exac Trac with the isocenter of the Linac." (*Id.* at 26-29, BrainLAB 112944-47). A calibration device, having five marker balls, designated as the "isocenter phantom, [*70] " is used to perform this alignment. (*Id.*, Fig. 11 at 26, BrainLAB 112944). This calibration process occurs after the cameras have been calibrated. The clinical user guides states that the system needs to be calibrated with the isocenter phantom at least once a day. (*Id.*)

Medtronic's expert witness, Dr. Taylor, testified that the isocenter phantom of the ExacTrac system is the "fiducial means" used to establish this three-dimensional coordinate framework. (Tr. at 996:13 -- 998:9). Dr. Taylor said that he had reviewed the computer code for the ExacTrac product and concluded that the locations of the markers on the isocenter phantom are used to perform the calculations that establish the workspace coordinate framework of the ExacTrac system. Dr. Taylor acknowledged that the isocenter phantom is not used to determine the relative locations of the cameras to each other. (Tr. at 1142:6-9).

BrainLAB does not dispute that the isocenter calibration phantom identifies the isocenter point of the Linac. Mr. Erbel, BrainLAB's project manager for the ExacTrac, testified by deposition as follows:

> Q. What does the isocenter phantom do?
>
> A. The isocenter phantom tells the ExacTrac [*71] system where the isocenter point of the linear accelerator is located and what the orientation of the XYZ axis of the machine is of the linear accelerator machine.

(Tr. at 2578:14-18). Dr. Taylor also agreed that the ExacTrac system uses the marker balls on the isocenter phantom to locate the isocenter of the Linac. (Tr. at 1141:25 -- 1142:12).

This evidence shows that the isocenter phantom is used to calculate a point within an already existing coordinate system. The isocenter phantom is not used for establishing a workspace coordinate framework because the framework is already in place when calibration with the isocenter phantom is performed.

BrainLAB's user guide for the ExacTrac describes a camera calibration process accomplished with a pyramid shaped device having 25 reflective markers. This pyramid-shaped device is referred to as a "calibration phantom." (Ex 307, at 20-26, BrainLAB 112938-43). When Medtronic responded to BrainLAB's motion for summary judgment of non-infringement, Medtronic argued that this pyramid shaped device with 25 fiducial points is a fiducial means used to "establish a workspace coordinate framework." [*72] (Pls.' Mem. in Opp'n to Defs.' Mot. for Summ. J. of Non-Infringement of the Heilbrun Patents, at 32-33). Between the time of the summary judgment briefing and trial, Medtronic changed its position about which calibration tool in the ExacTrac system serves as the fiducial means.

The court's claim construction reflects that establishing a workspace coordinate framework includes using the fiducial means for camera calibration. Dr. Taylor's testimony is inconsistent with that construction and cannot support the jury's verdict. The jury's verdict finding that BrainLab's ExacTrac product literally infringes claim 1 of the Heilbrun *101 patent* must be set aside.

Infringement of the Heilbrun 101 patent under the doctrine of equivalents by BrainLAB's ExacTrac product

Dr. Taylor opined only as to literal infringement of the ExacTrac product. (Tr. at 1041:3-5). Medtronic provided no particularized testimony supporting its claim of equivalence. The jury's finding that the ExacTrac infringes claim 1 of the Heilbrun *101 patent* under the doctrine of equivalents is without evidentiary support. *See Network Commerce, 422 F.3d at 1363.*

Remaining motions

Because the jury's verdicts of infringement must be set aside, [*73] there is no reason to address the defendants' motion for new trial, the plaintiffs' motion for prejudgment interest and the plaintiffs' motion for a permanent injunction. Judgment will enter for the defendants that there is no infringement.

Based on the foregoing, it is

ORDERED that the jury's verdict of infringement of *U.S. Patent No. 5,383,454* is set aside; it is

FURTHER ORDERED that the jury's verdict of infringement of *U.S. Patent No. 4,722,056* is set aside; it is

FURTHER ORDERED that the jury's verdict of infringement of *U.S. Patent Nos. 5,389,101* and *5,603,318* is set aside. The jury's verdict finding *U.S. Patent Nos. 5,389,101* and *5,603,318* valid will stand.

FURTHER ORDERED that the clerk shall enter judgment that the plaintiffs' patents are valid but not infringed by the defendants' products.

Dated: February 24, 2006

BY THE COURT:

s/Richard P. Matsch

Richard P. Matsch, Senior District Judge

JUDGMENT

Pursuant to the order on post-trial motions entered by Senior District Judge Richard P. Matsch on February 24, 2006, finding as a matter of law that *U.S. Patent No. 5,383,454* is not infringed by the defendants' VectorVision Classic, VectorVision<2>, VectorVision Compact, [*74] VectorVision Sky, Kolibri, and BrainSuite products; that *U.S. Patent No. 4,722,056* is not infringed as a

matter of law by the defendants' VectorVision Classic, VectorVision<2>, VectorVision Compact, VectorVision Sky, Kolibri, and BrainSuite products; and that *U.S. Patents Nos. 5,389,101* and *5,603,318* are not infringed as a matter of law by defendants' VectorVision Classic, VectorVision<2>, VectorVision Compact, VectorVision Sky, Kolibri, BrainSuite and ExacTrac products, and pursuant to the jury verdict that *U.S. Patent Nos. 5,389,101* and *5,603,318* are valid, it is

ORDERED AND ADJUDGED, that *U.S. Patent Nos. 5,389,101* and *5,603,318* are valid patents, and it is

FURTHER ORDERED that the plaintiffs' claims of infringement and this civil action are dismissed. Defendants are awarded their costs to be taxed pursuant to *D.C.Colo.LCivR 54.1*.

Dated: February 24, 2006

FOR THE COURT:

s/Richard P. Matsch

Richard P. Matsch, Senior District Judge